**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| **In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION** | **MDL NO. 1456** |
| | **Master File No. 01-CV-12257-PBS** |
| **THIS DOCUMENT RELATES TO ALL CLASS ACTIONS** | **Judge Patti B. Saris** |

**CONSOLIDATED MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT**

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Defying the Court's efforts to narrow the case and to eliminate unfounded, improperly pleaded claims, the Amended Master Consolidated Complaint ("AMCC") substantially expands the scope of this already sweeping litigation by including an array of new claims involving hundreds of new drugs. In effect, plaintiffs have launched the broadest possible attack on virtually the entire pharmaceutical industry in an attempt to challenge the manner in which prescription drugs are priced in this country.

The focus of this attack is once again the term "average wholesale price" ("AWP") – a pricing benchmark, according to plaintiffs, "from which hundreds of drug prices are derived in transactions throughout the pharmaceutical distribution chain." AMCC ¶ 5. The claims asserted in the AMCC now extend far beyond the realm of Medicare Part B to practically the entire marketplace for prescription drugs. Plaintiffs bring their claims on behalf of a class of individuals and entities who paid for any portion of the purchase price of a prescription drug where that price was based in any way on AWP. AMCC ¶ 595. In fact, this case primarily involves private institutional end-payors that paid for prescription drugs at some (perhaps substantial) discount off AWP through privately negotiated arm's-length transactions with intermediaries such as pharmacy benefit managers ("PBMs"). This dramatic shift in focus is reflected by the identity of the named plaintiffs: no individual Medicare Part B participant is named as a plaintiff in the AMCC.

Plaintiffs continue to contend that by reporting to third-party publishers AWPs that were not equal to providers' or intermediaries' average acquisition costs, defendants have violated the federal racketeering statute and the consumer fraud statutes of eleven states. In addition, they assert for the first time that defendants engaged in a multitude of civil conspiracies. These claims fail for several reasons.

First, despite clear instructions by the Court that they must plead their allegations of fraud with the particularity required by Rule 9(b), plaintiffs fail to do so. There are no specific allegations in the AMCC supporting plaintiffs' PBM claims. Moreover, although plaintiffs now attempt to catalog the specific drugs they contend are at issue in this case, along with the published AWPs for most – but not all – of these drugs from 1997 to 2002, they still do not explain how these published AWPs are "fraudulent." Instead, in most cases they simply allege that there is a difference between the published AWP and the prices paid by providers and PBMs. Despite the fact that plaintiffs themselves are third-party payors, they do not even allege what they paid – much less whether they paid the published AWPs or anything close to them. In addition, the AMCC still fails to allege purchasers for certain of the drugs that plaintiffs contend are included in the case.

Second, plaintiffs again fail to allege a viable RICO claim. In the hope of finding an enterprise that might withstand the Court's scrutiny, plaintiffs engage in a pleading game that results in 154 mini-enterprises, all of which fail as a matter of law. Plaintiffs also fail to allege that defendants conducted the affairs of the purported enterprises, and the AMCC includes no allegations showing that plaintiffs' injuries were proximately caused by defendants. Accordingly, the RICO claims must again be dismissed.

Third, plaintiffs' civil conspiracy claims must be dismissed because plaintiffs have failed to allege facts supporting such a conspiracy under Massachusetts law. Fourth, plaintiffs' state law consumer fraud claims must be dismissed because, among other things, the AMCC fails to allege adequately proximate cause. Finally, plaintiffs' renewed claims relating to multiple-

source drugs must be dismissed for the same reasons that the Court dismissed the same claims as alleged in the MCC – these claims simply do not fit the paradigm described in the complaint.

## STATEMENT OF THE CASE

### A. The Court's May 13, 2003 Memorandum and Order

On May 13, 2003, this Court granted in part, and denied in part, defendants' motion to dismiss the MCC. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172 (D. Mass. 2003) (hereinafter "*AWP Litigation*"). The Court dismissed plaintiffs' claims under RICO because plaintiffs had failed to allege a single viable RICO enterprise. *Id.* at 181-86. Because the defects in plaintiffs' enterprise allegations alone were fatal to plaintiffs' RICO claims, the Court did not reach defendants' arguments that the RICO claims should be dismissed because plaintiffs had failed to allege fraud or causation. *Id.* at 181 n.9. The Court also dismissed the association plaintiffs with respect to all claims for lack of standing. *Id.* at 194.

In addition, the Court dismissed a number of the claims alleged in the MCC for failure to satisfy the pleading standards for fraud set forth in Rule 9(b). In particular, the Court expressly ruled that any amended complaint must identify, for each defendant: "(1) the specific drug or drugs that were purchased from the defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." *Id.* at 194. The Court also ruled, *inter alia*, that plaintiffs' claims relating to multiple-source (including generic) drugs were dismissed, reasoning that such drugs "do not fit the paradigm described in the complaint." *Id.* at 194 & n.11.

**B. Amended Master Consolidated Class Action Complaint**

The AMCC is brought by eleven plaintiffs, including five ERISA-qualified employee benefit plans, a voluntary employee benefit plan, and five associations. AMCC ¶¶ 26-36. In contrast to the MCC, no individuals are included as named plaintiffs in the AMCC. The named plaintiffs purport to represent "consumers, self-insured employers, health and welfare funds, health insurers and other end payors for prescription drugs." AMCC ¶ 1.

Plaintiffs allege that defendants have engaged in a pattern of fraudulent conduct by "artificially inflating the AWPs for their drugs," which defendants allegedly knew were used not only by Medicare but also by "virtually all end payors" as the basis for prescription drug reimbursement. AMCC ¶¶ 134, 137-38, 140. While plaintiffs allege that, in the Medicare context, reimbursement for covered drugs is based on AWP by law, AMCC ¶ 145, they allege that, for private payors, reimbursement is set by contracts between health plans and PBMs that typically use AWP "less a certain percentage 'discount,'" AMCC ¶ 169.

Plaintiffs assert that defendants inflated the AWPs for their drugs so they could market the resulting "spread" between the published AWPs and actual acquisition costs for their products to providers and intermediaries, such as PBMs, in an effort to increase their respective sales and market shares. AMCC ¶¶ 4-6. As a result of this alleged conduct, defendants purportedly "directly caused Plaintiffs and the members of the Class to substantially overpay" for prescription drugs. AMCC ¶ 140. Plaintiffs' overpayment allegedly occurred in two contexts: (1) for drugs covered by Medicare Part B, and (2) for other drugs where reimbursement is based in some part on AWP. AMCC ¶¶ 141, 144, 148. Plaintiffs purport to capture this universe of drugs, referred to as AWPIDs, in their Appendix A, which catalogs over 300

different drugs and a combined total of over 1,500 different dosages of those drugs. Appendix A also simply recites the published AWPs for most – but not all – of these drugs and dosages, from 1997 through 2002.

Plaintiffs seek to represent all persons or entities that paid any portion of the purchase price of any drug manufactured by a defendant and identified in Appendix A at a price calculated by reference to the drug's published AWP (the "AWP Payor Class"), as well as a sub-class of the AWP Payor Class consisting of "[a]ll Third-Party Payors that . . . contracted with a PBM to provide to [their] participants a prescription drug manufactured by a Defendant Drug Manufacturer and identified in Appendix A [to the AMCC]" (the "Third-Party Payor Class"), regardless of the prices actually paid by these third-party payors. AMCC ¶ 595. Appendix B identifies each plaintiff that allegedly purchased certain of the drugs identified in Appendix A. No purchasers are identified for approximately one-third of the drugs listed in Appendix A.

Plaintiffs seek to recover under RICO (Counts I and II), and allege over 150 association-in-fact enterprises.[1] These enterprises include 66 bilateral associations-in-fact involving each of 22 defendant drug manufacturers and each publisher of pharmaceutical pricing compendia, *see* AMCC ¶¶ 624, 628, as well as an even greater number of bilateral associations-in-fact involving each of 22 defendant drug manufacturers and each of the four major PBMs, *see id.* ¶¶ 651, 661. These enterprises are, in essence, merely subparts of the Publisher and PBM enterprises that this Court previously found were not viable enterprises.

[1] Defendant Novartis Pharmaceuticals Corporation ("Novartis") is not named as a defendant in Counts I and II (RICO) or Count IX (civil conspiracy). Accordingly, any reference to "defendant" or "defendants" with respect to those Counts does not include Novartis.

Plaintiffs also seek to recover under the consumer protection statutes of eleven states (Count IV). In addition, they seek a declaratory judgment that "setting stated reimbursement prices above the actual average wholesale price for AWPIDs is unlawful, and that each Defendant Drug Manufacturer does so in violation of applicable law" (Count III). AMCC ¶ 681. Finally, plaintiffs allege that each of 22 defendants engaged in separate civil conspiracies with each of the four major PBMs in violation of state consumer protection laws, common law fraud, Medicare anti-fraud kickback statutes, and mail and wire fraud statutes (Count IX). Plaintiffs' remaining claims are alleged against the Together Rx Card defendants (Counts V-VIII, X).[2]

## ARGUMENT

### I. PLAINTIFFS' ATTEMPT TO EXPAND THIS CASE TO COVER HUNDREDS OF DRUGS FAILS TO SATISFY THE REQUIREMENTS OF RULE 9(B).

Rule 9(b)'s command to particularize fraud applies to each of plaintiffs' claims – whether under RICO or state consumer statutes or civil conspiracy laws – as they all sound in fraud. *See Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991) (RICO); *Hayduk v. Lanna*, 775 F.2d 441, 443-44 (1st Cir. 1985) (state law fraud claims alleged in federal court, including conspiracy claims, must satisfy Rule 9(b)). Moreover, in its May 13, 2003 Order, the Court held that plaintiffs would be required in the AMCC to comply with Rule 9(b). *See AWP Litigation*, 263 F. Supp. 2d at 194; *see also* Oral Arg. Tr. at 74. Indeed, the Court's order specifically stated that any amendment must allege "(1) the specific drug or drugs that were purchased from

[2] Plaintiffs' claims relating to the Together Rx Card are addressed in the separate memorandum of law filed by the Together Rx Card defendants.

defendant; (2) the allegedly fraudulent AWP for each drug, and (3) the name of specific plaintiff(s) that purchased the drug."[3] *AWP Litigation*, 263 F. Supp. 2d at 194.

Rather than heed the Court's admonition, plaintiffs have proffered a hefty complaint that substitutes bulk for substance and rote conclusory allegations for specific facts. In fact, plaintiffs seek to expand substantially the scope of this already sweeping litigation to cover hundreds of new drugs. Yet, they have not "particularize[d] exactly what the fraud is" or alleged a "fraudulent AWP" for the vast majority of the drugs named in the AMCC. This failure requires dismissal of all claims in the AMCC relating to these drugs.

**A. The PBM Allegations Are Plainly Deficient.**

In less than three pages of the 301-page AMCC, plaintiffs seek to widen this case "well beyond Medicare Part B," AMCC ¶ 168, to include "the drug benefits of 210 million people in the United States, or 70 percent of the nation's population." AMCC ¶ 170. Under plaintiffs' PBM theory, which involves hundreds of drugs outside of Medicare Part B: (1) the plaintiff benefit plans contract with PBMs so that their participants can obtain prescription drugs from retail pharmacies or via mail order directly from the PBM, AMCC ¶ 169; (2) the contracts that benefit plans typically negotiate with PBMs price drugs at a discount off AWP, *id.*; (3) defendants inflate the AWPs for their products so that they can market the spread between acquisition cost and AWP in order to "help manipulate the PBMs' profits from Plaintiffs and the classes," AMCC ¶ 172; and (4) defendants benefit from this scheme "by increasing the sales of

[3] *See also* Tr. of Oral Argument at 74 (Jan. 13, 2003) ("We're going to go drug by drug, if we go anywhere, because I can't be the supervisor of the entire pharmaceutical industry. You've got to meet 9(b) requirements. You've got to particularize exactly what drugs, exactly what the fraud is, which plaintiffs paid for what drugs.").